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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,803	07/01/2003	Eric Gervais	GOUD:031US	5065

7590 10/05/2007

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EXAMINER	
LEVY, NEIL S	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
10/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/611,803	GERVAIS ET AL.	
	Examiner	Art Unit	
	NEIL LEVY	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6,9 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The language is confusing; "the at least one active" and "comprises" pose interpretation problems, as an "ingredients" is seen as a single component. If more than one, we expect to find a mixture or composition. The meets and bounds of intended coverage are unknown. Claim 9 further confounds, as the vitamin of 6 is no longer the teratogen; now there are two.

Applicant points to diclectin as containing two actives; that is not the instant claim language.

The picture is immaterial to the tablet composition, & does not further limit nor provide patentable weight to the tablet composition.

Claims 6,9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pyridoxine HCL & doxylamine succinate tablets, does not reasonably provide enablement for suspicion of teratogenicity of actives desticned for pregnant women with indicia countering the teratogenicity with pregnancy friendliness..

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. A vitamin or vitamin and another active tablet bearing pregnancy friendly indicia,

Not a vitamin or another active suspected teratogen with a pregnancy friendly indicia.

There is no indication examiner can find that a suspect teratogen vitamin would be represented and then presented as pregnancy friendly.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6,9 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.
Encouraging the taking of a suspected teratogen is harmful, to the targeted population, pregnant women. FDA regulatory policies, if not public sentiment in this country, would not favor marketing a suspected teratogen by graphic presentations to encourage use by pregnant women.

Claim Rejections - 35 USC § 103

Claims 6,9 stand rejected under 35 U.S.C. 103(a) as being obvious over ORIFER F Prenatal Vitamin Supplement for pregnant women, September 25, 1996 in view of WO 97/48384.

Claims 6,9 strand rejected under 35 U.S.C. 103(a) as being obvious over WO 97/48384 in view of ORIFER F Prenatal Vitamin Supplement for pregnant women, September 25, 1996.

Double Patenting

Claims 6,9 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1 of Gervais et al U.S. Patent No. D501252 in view of Kirschner et al US006352713B1.

Gervais claims the instant illustration of a pregnant women stated to be a pregnancy friendly Indicia on a tablet. The Gervais patent is applicable to any tablet, however there is no indication of the actives. Kirschner shows pregnant women directed tablets of vitamins (col. 1, lines 5-15), inclusive of Pyridoxine(col. 12, lines 19-29,TABLE II).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made desiring to utilize a graphic design on a drug tablet to indicate prenatl consumption,to use one of
Gervais,on a tablet for prenatal consumptions, such as Kirschner' actives, in order to enhance acceptabity & consumtion by pregnant women.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Applicant's arguments filed 10/27/06 have been fully considered but they are not persuasive.
Applicant argues amendments were to address examiner's concern. This examiner finds claims are not clear, concise, and unambiguous, except as a design. As specification permits, precise claim language would overcome the rejection. Applicant also provides opinion declarations to support the lack of indicia on ORIFER dosage forms. Further, no design as claimed is in WO; only the technique to provide a design. While applicant argues obvious to try was not a standard, it is clear that any design could at the tine of WO, be imprinted on a tablet-with a clear cut expectation of success; no trial is needed. It remains only to apply a design representative of the effects or use expected-skull and cross bones for a warfarin or other poison tablet, the ORIFER picture, for use in pregnancy. KSR recently has re-enforced the concept of the use of logic by the artisan not requiring direction in a reference to lead the artisan to a conclusion of prima facie obviousness.

Applicant raises the issue of the references not providing non-teratogenic indicia. We have yet to see such indicia-an X over a depiction of a baby with a missing arm or two may serve in some minds to provide pregnancy friendly indicia of no teratogenecity, but could also result in misinterpretation, in examiner's opinion, with failure to use the tablet. In essence, examiner finds the issues are opinion-based. Applicant's indicia are not seen as presenting the concept of teratogenecity overcome with use of applicant's tablet, even though there is a presumption or suspicion that the active(s) are teratogenic. Alternatively, the depiction is seen as a fat lady; thus, the good market data. we are greatly impressed with the Koren DECLARATION. The statements of Dr. KOREN's opinions do not refute the issue examiner finds, of preventing as presumed teratogenic vitamin as a pregnancy friendly indicia embossed tablet. However, the 100+ pages of publications, children's plays and tales and music could serve as a basis for consideration of expectation by pregnant women of only positive outcome when recommended by one of Dr. KOREN's im;pressive credentials & child oriented background. We would still be left with concern for teratogenicity not overcome, however.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NEIL LEVY
Primary Examiner
Art Unit 1615

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